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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,058	01/15/2004	Ajay Bhatia	210121.515D1	4962

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EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/762,058	BHATIA ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/3/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed on 3/12/07 is acknowledged and entered.

The amendment to the specification page 105, line 25 is noted and entered. In view of the amending the specification to recite that SEQ.ID.NO:140 is CT875, the rejections of record are hereby withdrawn.

Status of Claims

2. Claims 19-26 are pending in the application.

Drawings

3. No drawings have been submitted in this application.

Information Disclosure Statement

4. Information Disclosure Statement filed on 10/03/05 is acknowledged and a signed copy is attached with this action.

Claim Rejections - 35 USC 112, first paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 19-25 are rejected under 35 U.5.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is referred to the interim guidelines on written description published at www.uspto.gov (O.G. published January 30, 2001). This is a written description rejection.

Claims 19-25 are drawn to a method of stimulating an immune response, said method comprising administering a composition comprising: (a) an isolated polypeptide comprising SEQID NO: 140; (b) an isolated polypeptide comprising an immunogenic portion of SEQ ID NO: 140 (examiner is considering this as a fragment of SEQ.ID.NO:140 and will be referred to fragment in the action hereafter); and (c) an isolated polypeptide having at least 95% identity to SEQ ID NO:140, and thereby stimulating an immune response specific for a (more than one) Chlamydia CT-875 protein (examiner is considering these as variants of SEQ.ID.NO:140 and will be referred to variant in the action hereafter) , a physiologically acceptable carrier and adjuvant, said adjuvant induces an immune response predominantly of the Th1 type, said adjuvant is selected from the group consisting of monophosphoryl lipid A, 3-de-o-acylated monophosphoryl lipid A, CpG- containing oligonucleotides, saponins, QS21, the adjuvant is an aminoalkyl glucosaminide 4-phosphate, said glucosaminide 4- phosphate is RC-529.

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a product itself logically cannot adequately describe a method of using that product.

Thus, the instant specification may provide an adequate written description of an isolated polypeptide comprising an immunogenic portion of SEQ ID NO:140 and an isolated polypeptide having at least 95% identity to SEQ ID NO:140, capable of stimulating an immune response specific for a

Chlamydia CT-875 protein, per Lilly by structurally describing a representative number of variants/fragments or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not describe protein having 95%identity to SEQ.ID.NO:140 or an isolated polypeptide comprising an immunogenic portion of SEQ ID NO:140, capable of stimulating an immune response specific for a Chlamydia CT-875 protein required to practice the claims 19-26 in a manner that satisfies either the Lilly or Enzo standards. The specification does not provide the complete structure of any variant/fragment of SEQ ID NO:140 as claimed, nor does the specification provide any partial structure of such variant/fragment , nor any physical or chemical characteristics of the variant/fragment nor any functional characteristics coupled with a known or disclosed correlation between structure and function other than SEQ ID NO:140. Although the specification discloses an isolated recombinant protein comprising the amino acid sequence SEQ.ID.NO:140, recognized human T-cell lines from E Serovar and does not provide a description of variant/fragment recognized human T-cell lines from E Serovar that would satisfy the standard set out in Enzo.

The specification also fails to describe the variant/fragment by the test set out in Lilly. The specification describes only isolated polypeptide comprising the amino acid sequence SEQ.ID.NO:140 Therefore, it necessarily fails to describe a "representative number" of such species. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

Thus, the specification does not provide an adequate written description of the protein which has 95% sequence identity to the amino acid sequence of SEQ.ID.NO:140 or an isolated polypeptide comprising an immunogenic portion of SEQ ID NO:140 that is required to practice the claimed invention.

Thus, the specification fails to teach the claimed variant/fragment and does not satisfy the written description guidelines because an isolated protein which has at least 95% sequence identity to SEQ ID NO:140 and an isolated polypeptide comprising an immunogenic portion of SEQ ID NO:140. Therefore, the method of stimulating an immune response using said variants that are specific for Chlamydia CT875 does not adequately described by this specification. The specification fails to teach the structure or relevant identifying characteristics sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed.

Claims 19-25 do not comply with 35 USC 112, first paragraph because it is not supported by an adequate written description in the specification.

7. Claims 19-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of stimulating an immune response to an isolated polypeptide , SEQID NO: 140 said method comprising administering a composition comprising: an isolated polypeptide comprising the amino acid sequence, SEQID NO: 140 a physiologically acceptable carrier and adjuvant, said adjuvant induces an immune response predominantly of the Th1 type, said adjuvant is selected from the group consisting of monophosphoryl lipid A, 3-de-o-acylated monophosphoryl lipid A, CpG- containing oligonucleotides, saponins, QS21, aminoalkyl glucosaminide 4-phosphate, said glucosaminide 4-phosphate is RC-529, said polypeptide is the amino acid sequence SEQ ID NO: 140 does not reasonably provide enablement for (b) an isolated polypeptide comprising an immunogenic portion of SEQ ID NO: 140 or polypeptide having at least 95% identity to SEQ ID NO:140, and thereby stimulating an immune response specific for a Chlamydia CT875 protein (claim 19) , a physiologically acceptable carrier and adjuvant (claims 20 and 21) , said adjuvant induces an immune response predominantly of the Th1 type (claim 22) , said adjuvant is selected from the group consisting of monophosphoryl lipid A, 3-de-o-acylated monophosphoryl lipid A, CpG- containing oligonucleotides, saponins, QS21 and combinations thereof (claim 23), the adjuvant is an aminoalkyl glucosaminide 4-phosphate (claim 24), said glucosaminide 4- phosphate is RC-529 (claim 25) . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Claims 19-25 are broadly drawn to a method of stimulating an immune response, said method comprising administering a composition comprising: (a) an isolated polypeptide comprising SEQID NO: 140; (b) an isolated polypeptide comprising an immunogenic portion of SEQ ID NO: 140; and (c) a isolated polypeptide having at least 95% identity to SEQ ID NO:140, and thereby stimulating an immune

response specific for a Chlamydia CT-875 protein, a physiologically acceptable carrier (claim 19) and adjuvant, said adjuvant induces an immune response predominantly of the Th1 type, said adjuvant is selected from the group consisting of monophosphoryl lipid A, 3-de-o-acylated monophosphoryl lipid A, CpG- containing oligonucleotides, saponins, QS21, the adjuvant is an aminoalkyl glucosaminide 4-phosphate, said glucosaminide 4- phosphate is RC-529, said polypeptide is the amino acid sequence SEQ ID NO: 140 (claim 26).

This means that claimed method uses broadly drawn undefined isolated polypeptide having at least 95% identity to SEQ ID NO:140 or isolated polypeptide comprising an immunogenic portion to induce an immune response that is specific for a Chlamydia CT-875 protein which is not limited to SEQ ID NO:140.

The specification (page 106) teaches preparation of recombinant protein comprising 598 amino acids as set forth in the SEQ.ID.NO 140, which is designated as CT-875. The specification exemplifies that this recombinant protein recognized the T-cell clones obtained from Chlamydia trachomatis Serovar E patients as shown in Table IV.

The teaching of the specification cannot be extrapolated to enable the scope of the claims because the claims are drawn to include variants or polypeptide comprising an immunogenic portion (i.e., fragment) of SEQ.ID.NO: 140. However, disruption of the sequence by 5% or fragment thereof, sufficient to induce an immune response that would recognize *C. trachomatis* is acknowledged to be unpredictable because the specification fails to disclose which residues are critical to induce specific immune response that recognize Chlamydia . The effects of any deletion or change in a polypeptide SEQ.ID.NO: 140 on the ability to induce an immune response that is specific to SEQ ID NO:140 are unpredictable because protein chemistry is probably one of the most unpredictable areas of biotechnology and the art teaches that the significance of any particular amino acid sequences (i.e. fragments) for different aspects of biological activity cannot be predicted a priori and must be determined empirically on a case-by-case basis (Rudinger et al, in "PEPTIDE HORMONES", edited by Parsons, J.A., University Park Press, June 1976, page 6).

In particular, neither the specification nor the art of record define which amino acid residues are critical to for stimulating an immune response that is specific for CT875 protein,SEQ ID NO: 140. As drawn to antibodies, Bowie et al (Science, 1990, 257:1306-1310) teaches that an amino acid sequence encodes a message that determines the shape of a protein and determines the ability of said protein to fold into unique three-dimensional structures that allows them to function. Bowie further teaches that certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (p. 1306, cols 1 and 2). Clearly, the three dimension structure of a protein is critical to the production of antibodies given the teaching of Herbert et al (The Dictionary of Immunology, Academic Press, 3rd Edition, London, 1985, pages 58-59). Herbert et al who specifically teach that an epitope is the region on an antigen molecule to

which antibody specifically binds. B cell epitopes on protein antigens are of variable size comprising up to about 20 amino acids. Antibodies bind in a more or less exact three dimensional fit with an epitope. This may be formed from residues on different regions of a protein antigen molecule which, in the native state, are closely apposed due to protein folding.. Thus the three-dimensional structure of the protein molecule may be essential for antibody binding. (p. 58). However, neither the specification nor the art of record provide teachings that provide information about the residues critical for epitopes required for the establishment of an immune response that will produce antibodies that recognize full-length SEQ ID NO: 140. This information appears to be critical because the art recognizes (see Bowie above) that it is the protein sequence that determines the three dimensional shape of a protein and Herbert et al specifically state that antibodies bind in a more or less exact three dimensional fit and suggests that the three-dimensional structure of the protein molecule may be essential for antibody binding.

Roitt et al (Immunology, 1993, Mosby, St. Louis, p 7.7-7.8) teach that although it is possible to produce antibodies to almost any part of an antigen, this does not normally happen in an immune response. It is usually found that only certain areas of the antigen are particularly antigenic, and that a majority of antibodies bind to these regions. These regions are often at exposed areas on the outside of the antigen, particularly where there are loops of polypeptide that lack a rigid tertiary structure (p.7.7-7.8). This is exemplified by the teaching of Holmes (Exp. Opin.Invest. Drugs, 2001, 10(3):511-519) who teaches that rabbits were immunized with synthetic peptides which in each case generated high anti-peptide specific immunoreactivities, however, none of the antibodies exhibited binding to the full length antigen. The author concludes that 'Presumably, expression of these epitopes in the context of the protein was important and affected the antibody binding ability' (p. 513, col 1). Furthermore, the specification does not take into account the 3 dimensional folding of the native molecule, nor its glycosylation or other post-translational modifications and other characteristics which are of significant importance in an antibody response. Peptides or synthetic antigens cannot effectively substitute for the natural tertiary and quarterary structure of a protein in a physiological situation. Given this teaching, even if the claimed antigen consisted of portions of SEQ ID NO:140 it would not be possible to determine with any predictability whether the antibodies produced from portion fragment that is specific for SEQ ID NO:140 actually bind to SEQ ID NO: 140 in the absence of guidance from the specification.

Further, there is no teaching in the specification of which or whether or not the epitopes are linear or comprise 3-dimensional structures. In particular, Greenspan et al (Nature Biotechnology, 1999, 7:936-937) teaches that defining epitopes is not as easy as it seems. Even when the epitope is defined, in terms of the spatial organization of residues making contact with ligand, then a structural characterization of the molecular interface for binding is necessary to define the boundaries of the epitope (page 937, 2nd column). Thus, it is clear that although the specification provides hundreds, perhaps thousands of putative immunogens, it is not possible to predictably distinguish which of those sequences will function

as claimed and undue experimentation would be required to distinguish between those that function as claimed and those that do not.

Further, as drawn to immune response predominantly of the Th1 type, Herbert et al, Supra, teaches that T-cells recognize peptide fragments which have been processed by an accessory cell and presented in the cleft of a class IMHC antigen or a class II MHC antigen and that a continuous primary sequence is necessary for T cell recognition (p. 58). It is obvious that T cell epitopes and antibody epitopes are not the same. However, the issues drawn to the lack of guidance in the specification as to critical residues and polypeptide fragments required for Th1 response are relevant to this limitation as well. Further, even if the peptides claimed were 100% identical to specific portions of SEQ ID NO:140 it would not be possible to determine with any predictability which of the portions of SEQ ID NO:140 would predominantly induce Th1 response that would be recognized by T-cells from patients infected with Chlamydia.

The specification provides no working examples demonstrating (i.e., guidance) enablement for variant/fragment of SEQ.ID.NO:140. Since the specification does not teach how to make variants/fragments of the protein SEQ.ID.NO: 140 that will function as claimed, the skilled artisan would not be able to use the claimed variant/fragment in a method . In view of the unpredictability of the art, the lack of teachings of the specification, it would require undue experimentation on the part of the skilled artisan to practice the invention as claimed.

Claim Rejections - 35 USC 112, second paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 19-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19 –26 are rejected as being vague for the recitation of "CT-875 protein". The recitation of the term CT-875 appear to be a lab designated terminology. Since this terminology change from lab to lab or the same designation can be used for totally different protein, it is proper to recite the structure of the protein by sequence identification number .

Claims 19 –26 are rejected for the recitation of " a Chlamydia CT 875protein" because recitation of "a" in the claim indicates more than one Chlamydia CT 875protein , however the specification teaches only one CT-875 protein, SEQ.ID.NO:140, therefore, the claims are confusing and the metes and bounds of a Chlamydia CT 875 protein is unclear.

Claim Rejections - 35 USC 102

10. A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

11. Claims 19-23 are rejected under 35 U.S.C. 102 (e), as being anticipated by Probst et al U S Patent 6,432,916.

Claims 19-23 are drawn to a method of stimulating an immune response, said method comprising administering a composition comprising: (a) an isolated polypeptide comprising SEQID NO: 140; (b) an isolated polypeptide comprising an immunogenic portion of SEQ ID NO: 140 ; and (c) an isolated polypeptide having at least 95% identity to SEQ ID NO:140, and thereby stimulating an immune response specific for a Chlamydia CT-875 protein and a physiologically acceptable carrier and adjuvant, said adjuvant induces an immune response predominantly of the Th1 type, said adjuvant is selected from the group consisting of monophosphoryl lipid A, 3-de-o-acylated monophosphoryl lipid A, CpG- containing oligonucleotides, saponins, QS21,

Probst et al disclose a method of stimulating an immune response comprising administering an isolated polypeptide comprising an immunogenic portion of SEQ ID NO: 290 (see the sequence alignment below) The polypeptide together with physiologically acceptable carrier buffer and adjuvant that elicits a predominantly Th1-type response include, for example, a combination of monophosphoryl lipid A, preferably 3-de-O-acylated monophosphoryl lipid A (3D-MPL), together with an aluminum salt (see column 33, lines 2-5 and 49-67 and) generate antigen-specific T-cell lines may be generated by in vivo immunization with short peptides corresponding to immunogenic portions of the disclosed polypeptides.

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S-09-556-877-296
; Sequence 296, Application US/09556877
; Patent No. 6432916
; GENERAL INFORMATION:
;  APPLICANT:  Probst, Peter
;  APPLICANT:  Bhatia, Ajay
;  APPLICANT:  Skeiky, Yasir
;  APPLICANT:  Fling, Steve
;  APPLICANT:  Maisonneuve, Jeff
;  TITLE OF INVENTION:  COMPOSITIONS AND METHODS FOR TREATMENT AND
;  TITLE OF INVENTION:  DIAGNOSIS OF CHLAMYDIAL INFECTION
;  FILE REFERENCE:  210121.469C5
;  CURRENT APPLICATION NUMBER: US/09/556,877
;  CURRENT FILING DATE:  2000-04-19
;  NUMBER OF SEQ ID NOS:  305
;  SOFTWARE:  FastSEQ for Windows Version 3.0/4.0
; SEQ ID NO 296
;   LENGTH: 124
;   TYPE: PRT
;   ORGANISM: Chlamydia
US-09-556-877-296

  Query Match             9.7%;  Score 58;  DB 2;  Length 124;
  Best Local Similarity   100.0%;  Pred. No. 1.1e-46;
  Matches   58;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;
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Qy        527 RYQLQNMDVEAGFREAVYASFVAGMYNYVVTQPQERIPNSQQVEGILRDMLTNGSQTF 584
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         53 RYQLQNMDVEAGFREAVYASFVAGMYNYVVTQPQERIPNSQQVEGILRDMLTNGSQTF 110
```

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
13. Claims 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Probst et al U S Patent 6,432,916 in view of Baldridge et al J.Endotoxin Research 2002; 8(6); 453-8 (at present the examiner is sending the abstract only) .

Claims 19-23 have been discussed and rejected supra in para# 11. The art does not teach adjuvant aminoalkyl glucosaminide 4-phosphate, RC-529. However, Baldridge et al teach adjuvant intranasal administration of RC-524 or RC-529 to mice 2 days prior to a lethal influenza challenge provided significant protection in each case. The art suggests activation of the innate immune response by AGPs appears to involve activation of Toll-like receptor 4 (TLR4) to elicit a protective effect (see abstract).

It would have been prima facie obvious to one of ordinary skill in the art at the time invention was made to use the readily available adjuvant aminoalkyl glucosaminide 4-phosphate, RC-529 with isolated polypeptide comprising an immunogenic portion of SEQ ID NO: 290 with physiologically acceptable

carrier buffer to generate protective immune response. Therefore, an artisan of ordinary skill would have been motivated to use adjuvant RC-529 because Baldridge clearly suggests that use of RC-529 induces innate immune response.Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to use isolated polypeptide comprising an immunogenic portion of SEQ ID NO: 290 as taught by Probst et al U S Patent 6,432,916 with an adjuvant RC-529 as taught by **Baldridge et al** because *the adjuvant has shown to induce protective immune response.* The claimed invention is prima facie obvious over Probst in view of **Baldridge et al** absent any convincing evidence to the contrary.

Status of Claims

14. No claims are allowed.

Conclusion

15. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600

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